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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,089	08/21/2003	David Ernest Hartley	PA-5340 -RFB	7302

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EXAMINER	
TOWA, RENE T	

ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,089	HARTLEY ET AL.	
	Examiner	Art Unit	
	Rene Towa	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,7-9,11,12,14,28 and 35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,7-9,11,12,14,28 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is responsive to an amendment filed November 7, 2006. Claims 1, 3-4, 7-9, 11-12, 14, 28 and 35 are pending. Claims 1, 3-4, 9, 14 and 28 have been amended. New claim 35 has been added.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. From the language of claim 1, it is unclear whether or not the distal curve extends from the distal zone (which is clearly claimed as a separate element from the central zone) or whether the distal curve extends from a portion of the central zone in which case the distal curve overlaps both the distal zone and the central zone and therefore is not merely included in the distal zone.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1, 4, 7-9 & 11-12, 14 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clayman et al. (US 6,716,183) in view of Radisch, Jr. (US 5,295,493) further in view of Sakamoto et al. (US 4,925,445).

In regards to claims 1, 4, 7-9 & 11-12, Clayman et al. disclose(s) a guide wire to assist in anatomic deployment, the guide wire having zones of varying stiffness comprising:

an elongate central zone 18 of high stiffness, and substantally constant diameter along its length;

a proximal zone 21 of transition from high stiffness to semi-stiffness and having a length; and

a tapered segmental distal zone 16 of transition from high stiffness to being relatively flexible;

wherein the proximal zone 21 comprises a tapered mandrel with a proximal wire coil 41 of substantially constant coil diameter on and extending along the tapered mandrel;

wherein the proximal wire coil is laser welded to the tapered mandrel (see fig. 7; column 6/lines 45-48);

wherein the proximal wire coil terminates in a rounded tip 50 (see fig. 2) ;

wherein the distal zone 16 comprises in order from the central zone 18, a tapered mandrel portion 30 and a portion of constant reduced diameter 25 with a distal wire coil 34 of substantially constant coil diameter on and extending along the tapered mandrel portion 30 and the portion of constant reduced diameter;

wherein at least a portion the guide wire is radiopaque (i.e. the coil made out of stainless steel, see column 5/lines 36-37) (see figs. 1A-B; column 4/lines 6-14, 30-32 & 54-67; column 5/lines 1-18 & 26-28).

Clayman et al. disclose a guide wire, as described above, that teaches all the limitations of the claims except Clayman et al. do not expressly teach a distal zone that includes a pre-formed curve. However, Radisch, Jr. discloses a guide wire comprising a distal zone wherein the distal zone comprises a distal pre-formed curve (22, 30, 40, 30a) with a radius; wherein the central zone comprises a stainless steel mandrel (see figs. 1-1A, 2-2A, 3-3A & 4-4A; column 2/lines 52-68; column 3/lines 1-6 & 24-28; column 4/lines 15-22, 30-42 & 58-67; column 5/lines 12-18 & 33-45).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a guide wire similar to that of Clayman et al. with a pre-formed curve distal zone similar to that of Radisch, Jr. so that the guide wire conforms to the general anatomical shape of the body cavity to thereby hold the guide wire in its prepositioned place (see Radisch, Jr., column 2/lines 52-68; column 3/lines 24-28). Moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a guide wire similar to that of Clayman et al. with a stainless steel central portion similar to that of Radisch, Jr. in order to provide a core wire of a suitably strong material that can be formed and maintained in a desired shape (see Radisch, Jr., column 4/lines 18-22).

Clayman et al. as modified by Radisch, Jr. disclose a guide wire, as described above, that teaches all the limitations of the claims except Clayman et al. as modified by Radisch, Jr. do not explicitly teach a tip curve. However, Sakamoto et al. disclose a guide wire comprising a tip curve (see figs. 1 & 5A-D).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a guide wire similar to that of Clayman et al. as modified by Radisch, Jr. with a tip curve similar to that of Sakamoto et al. in order to prevent the tip portion of the guide wire from piercing the wall of the blood vessel (see Sakamoto et al., column 5/lines 57-64).

More in regard to claim 1, Clayman et al. as modified by Radisch, Jr. and Sakamoto et al. disclose a guide wire, as described above, that teaches all the limitations of the claims except for a proximal zone length of 3 cm to 20 cm, a distal zone pre-formed curve radius of 5 cm to 15 cm, and tip zone radius of 5 to 20 mm. Instead Clayman et al. as modified by Radisch, Jr. and Sakamoto et al. teach a proximal zone having a length, a distal zone pre-formed curve having a radius, and tip zone having a radius.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide a guide wire having a distal zone pre-formed curve radius of 5 cm to 15 cm, and tip zone radius of 5 to 20 mm because the Applicant has not disclosed that a distal zone pre-formed curve radius of 5 cm to 15 cm, and tip zone radius of 5 to 20 mm are critical and provide an advantage, are used for a particular purpose, or solve a stated problem. One of ordinary skill in the

art, furthermore, would have expected the guide wire of Clayman et al. as modified by Radisch, Jr. and Sakamoto et al., and Applicant's invention to have performed equally well because the guide wire would perform the same function of:

providing sufficient flexibility to the proximal section so as to facilitate retrograde access insertion into the guide channel of an instrument (see Clayman et al., column 4/lines 60-63; see Radisch, Jr., column 2/lines 52-57);

providing a distal zone pre-formed curve radius sufficient for conforming to the general anatomical shape of the body cavity to thereby hold the guide wire in its prepositioned place (see Radisch, Jr., column 2/lines 52-68; column 3/lines 24-28; see Sakamoto et al., column 5/line 65 to column 6/line 2); and,

providing a tip zone radius sufficient to prevent the tip portion of the guide wire from piercing the wall of the blood vessel (see Sakamoto et al., column 5/lines 57-64). .

Therefore, it would have been prima facie obvious to modify Clayman et al. as modified by Radisch, Jr. and Sakamoto et al. to obtain the invention as specified in claim 1 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Clayman et al. as modified by Radisch, Jr. and Sakamoto et al.

In regards to claim 14, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a guide wire similar to that of Clayman et al. as modified by Radisch, Jr. and Sakamoto et al. with a distal curve that overlaps the distal and central zone since such a modification would amount to an obvious design choice that would the same purpose of smoothly increasing the flexibility

of the guide wire towards the distal end thereof; and prevent breakage of the guide wire at said overlapping portion (see Sakamoto et al., column 5/lines 50-56).

6. Claims 28 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clayman et al. ('183) in view of Radisch, Jr. ('493) further in view of Sakamoto et al. ('445) even further in view of Ferrera (US 6,165,140).

Clayman et al. as modified by Radisch, Jr. and Sakamoto et al. disclose a guide wire, as described above, that teaches all the limitations of the claims except for a radiopaque guide wire or a polytetrafluoroethylene coated wire coil.

However, Ferrera discloses a guide wire comprising a radiopaque guide wire and a wire coil having a portion 40 coated with polytetrafluoroethylene (PTFE) (see column 3/lines 42-48).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a guide wire similar to that of Clayman et al. as modified by Radisch, Jr. and Sakamoto et al. with a PTFE coating similar to that of Ferrera in order to improve the lubricity of the guide wire and fixedly maintain the wire coil in place. Moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a guide wire similar to that of Clayman et al. as modified by Radisch, Jr. and Sakamoto et al. with a radiopaque coil similar to that of Ferrera in order to increase the visibility of the guide wire under fluoroscopy.

Response to Arguments

7. Applicant's arguments filed November 7, 2006 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6,254,550 to McNamara et al. discloses a preformed wire guide.

US 7,048,695 to Schwager discloses a guiding aid.

US 5,363,847 to Viera discloses a guidewire having double distal portions.

US 5,365,943 to Jansen discloses an anatomically matched steerable PTCA guidewire.

US 4,971,490 to Hawkins discloses a flexible guide wire with improved mounting arrangement for coil spring tip.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RTT

MARK S. GRAHAM
PATENT EXAMINER
ART UNIT 3736